

REMARKS

In response to the Office Action mailed May 11, 2007, Applicants submit the following remarks. The one-month extended deadline to respond is September 11, 2007. Applicants submit herewith a one-month Petition for Extension of Time and the appropriate fee. Therefore, Applicants believe that this response is being timely filed. Applicants believe that the fees submitted herewith are sufficient. However, in the event that Applicants are incorrect in their assumption, please charge any necessary fee to Deposit Account No. 23-2415, referencing Docket No. 33392-712.201.

By the above amendments, Claims 9 and 20 have been revised to further specify that the coating is disposed on at least one of the plurality of stratum corneum-piercing microprotrusions to release the vasoconstrictor into the skin when the coating is dissolved, resulting in the inhibition of bleeding and a decrease in blood flow at the site of application of the device. This amendment is supported by the specification as originally filed. See, for example, page 15, lines 17-27. Accordingly, entry of the amendment is proper and respectfully requested.

Provisional Double Patenting

Claims 1-20 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-19 of copending Application No. 11/259,010. Claims 1-20 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-34 of copending Application No. 11/201,617. Claims 1-20 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-81 of copending Application No. 11/084,636.

Applicants respectfully request that the double patenting rejections be stayed in abeyance until the present application is indicated to be otherwise allowable. At such time, Applicants will submit a Terminal Disclaimer, if appropriate.

Claim Rejections – 35 USC §112

Claim 12 and 13 were rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At the outset, Applicants note that Claims 12 and 13 do not recite analogs or salts. It would appear that the rejection may be directed to Claim 11. Applicants respectfully submit that the “analog” and “salt” language recited in Claim 11 is definite and supported in the specification and claims as originally filed. However, in order to expedite allowance of the subject application, Applicants have amended Claim 11 to remove the allegedly objectionable language. Applicants reserve the right to pursue the cancelled subject matter in the future.

Accordingly, it is believed that the rejection under 35 U.S.C. 112, second paragraph has been rendered moot. Withdrawal of the rejection is respectfully requested.

Claim Rejections – 35 USC §103

Claims 9-20 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over WO 02/074173 (WO ‘173) in view of US 6,432,986 (the ‘986 patent). This rejection is traversed for at least the following reasons.

As defined by amended Claim 1, the present invention relates to a device for transdermally delivering a biologically active agent and a vasoconstrictor, comprising: a member having a plurality of stratum corneum-piercing microprotrusions; and a dry coating disposed on at least one of the plurality of stratum corneum-piercing microprotrusions, the coating including a biologically active agent and a vasoconstrictor. The coating is disposed on at least one of the plurality of stratum corneum-piercing microprotrusions to release the vasoconstrictor into the skin when the coating is dissolved, resulting in the inhibition of bleeding and a decrease in blood flow at the site of application of said device

The combination of WO ‘173 and the ‘986 patent fails to suggest each feature of the presently claimed invention. Neither WO ‘173, nor the ‘986 patent disclose coating is disposed on at least one of the plurality of stratum corneum-piercing microprotrusions to release the vasoconstrictor into the skin when the coating is dissolved, resulting in the inhibition of bleeding and a decrease in blood flow at the site of application of said device.

Moreover, neither WO ‘173, nor the ‘986 patent suggest the advantages obtained by the present invention. Illustration of such advantages is provided in Example 1 and Figures 3-5 discussed therein.

Accordingly, the rejection under 35 U.S.C. 103(a) should be withdrawn and such favorable action is respectfully requested.

CONCLUSION

Applicants believe that, for the reasons explained above, all of the pending claims are in condition for examination on the merits and such action is respectfully requested. The one-month extended deadline to respond is September 11, 2007. Applicants submit herewith a one-month Petition for Extension of Time and the appropriate fee. Therefore, Applicants believe that this response is being timely filed. Applicants believe that the fees submitted herewith are sufficient. However, in the event that Applicants are incorrect in their assumption, please charge any necessary fee to Deposit Account No. 23-2415, referencing Docket No. 33392-712.201.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (858) 350-2337.

Respectfully submitted,

Date: September 11, 2007

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